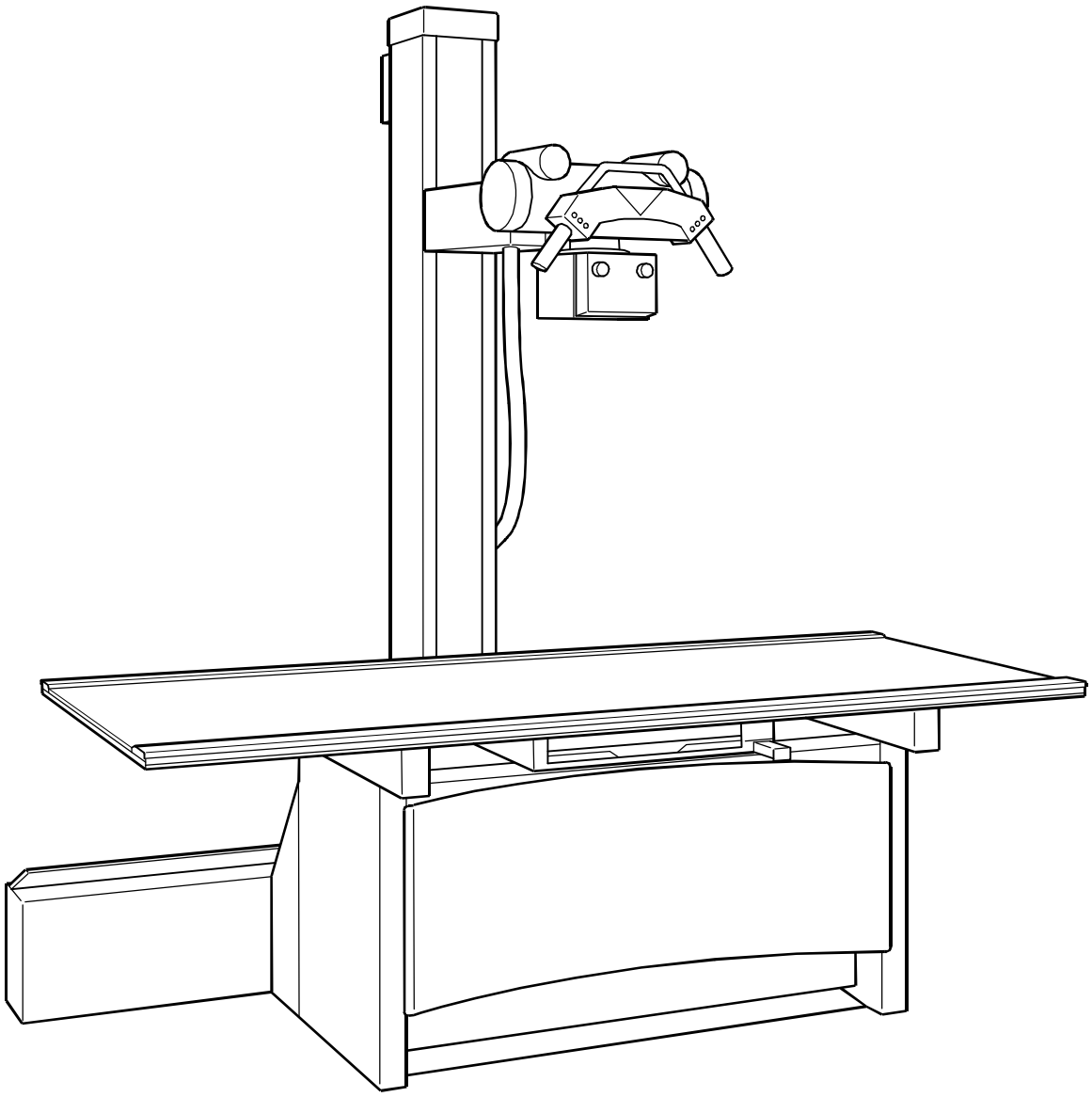
Operating Instructions CS 2000



CE 0125

English Edition

Rev. 03 © 1999 Hans Pausch Röntgengerätebau Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

CONTENTS ***Page***

Important Note ***3***

Safety-technical Remarks
- Regulations 3

Product Safety ***4***
- Electrical Safety 4
- Mechanical Safety 4
- Crush Zones 4
- Radiation Safety 5
- Explosion Protection 6
- Electromagnetic Interference, EMI 6
- Classification per IEC 601-1-1 6
- EC Conformity 6
- Environmental Conditions for Operation 6
- Disposal 6

Design Features
- Design 7

General
- Brief Description 8
- Area of Applicability 9
- Important Note 9

Setup
- Space Requirement 10
- Room Height 10
- Connection 10
- Line Power 10
- Al Equivalency Value 10

Control Elements
- Location 11
- Explanation of Symbols/Function 12
- Setting the Exposure Position/Exposure 14
- Accessories 16

Maintenance
- Important Note 18
- Testing by the Operator 18
- Testing by Customer Service 18
- Cleaning 18
- Disinfection 19
- EEC Guideline 93/42 Regarding Medical Products 19

Placement of Model Labels
- Labeling 20

Rev. 03 © 1999 Hans Pausch Röntgengeräte Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

IMPORTANT NOTE

Proper use of this product by operating personnel requires knowledge of these **OPERATING INSTRUCTIONS**; these must be studied prior to starting up the equipment.

This radiographic equipment may be operated only by personnel who possess the required specialized knowledge of radiation safety or who are familiar with radiation safety and who have been instructed in the operation of the radiographic equipment.

The operator is always responsible for maintaining the regulations that apply for operation of the radiographic equipment.

SAFETY-TECHNICAL REMARKS

Regulations

If there are legally specified regulations regarding the operation of radiographic equipment, it is the responsibility of the operator to observe them.

In the interest of safety for patient, operating personnel as well as for third parties, tests which assure the operating reliability and functionality of the product must be performed in accordance with the Maintenance Instructions in intervals of 12 months.
We request that you contact your customer service department regarding performance of these tests.

If tests are required in shorter intervals in order to comply with national specifications or regulations, it is absolutely necessary to observe them.

Modifications and additions made to the product must be in accordance with legal regulations as well as with generally accepted rules of the technology.

As the manufacturer of the radiographic equipment, we can assume responsibility for the safety-technical features of the product only if:
any maintenance, repair and modification on it is carried out only by us or by facilities that have been authorized by us for this purpose, and if there is a failure of parts which affect the safety of the product, such parts are replaced with original spare parts.

When performing this work, we recommend that written confirmation regarding the nature and extent of work be requested from the person performing the work, and if applicable, include any changes made in nominal values or to the operating range. In addition, the company performing the work, the date and a signature should be included.

Prior to daily use, the user must assure himself that all devices provided for safety are functional and that the product is operational.

If the operator of the radiographic equipment wishes to combine it with other products, components or assemblies, and this capability is not clear from the technical data, he must assure that the safety of patients as well as of operating personnel is not adversely affected by the intended combination by contacting us as the manufacturer of the equipment or by contacting someone who has specialized knowledge of the equipment.

Rev. 03 © 1999 Hans Pausch Röntgengerätebau Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

PRODUCT SAFETY

Electrical Safety

Only specially trained maintenance personnel may remove the covers and panels on the radiographic equipment.

This radiographic product may be operated only in medical rooms that meet the requirements of VDE 0107.
It is designed for a permanent connection with universal isolation from the power source (IEC 601, Chap. 57.1).

Mechanical Safety

Please make sure that neither the patient nor you can reach into the movement path of the radiographic equipment or that parts of clothing can be caught by it.

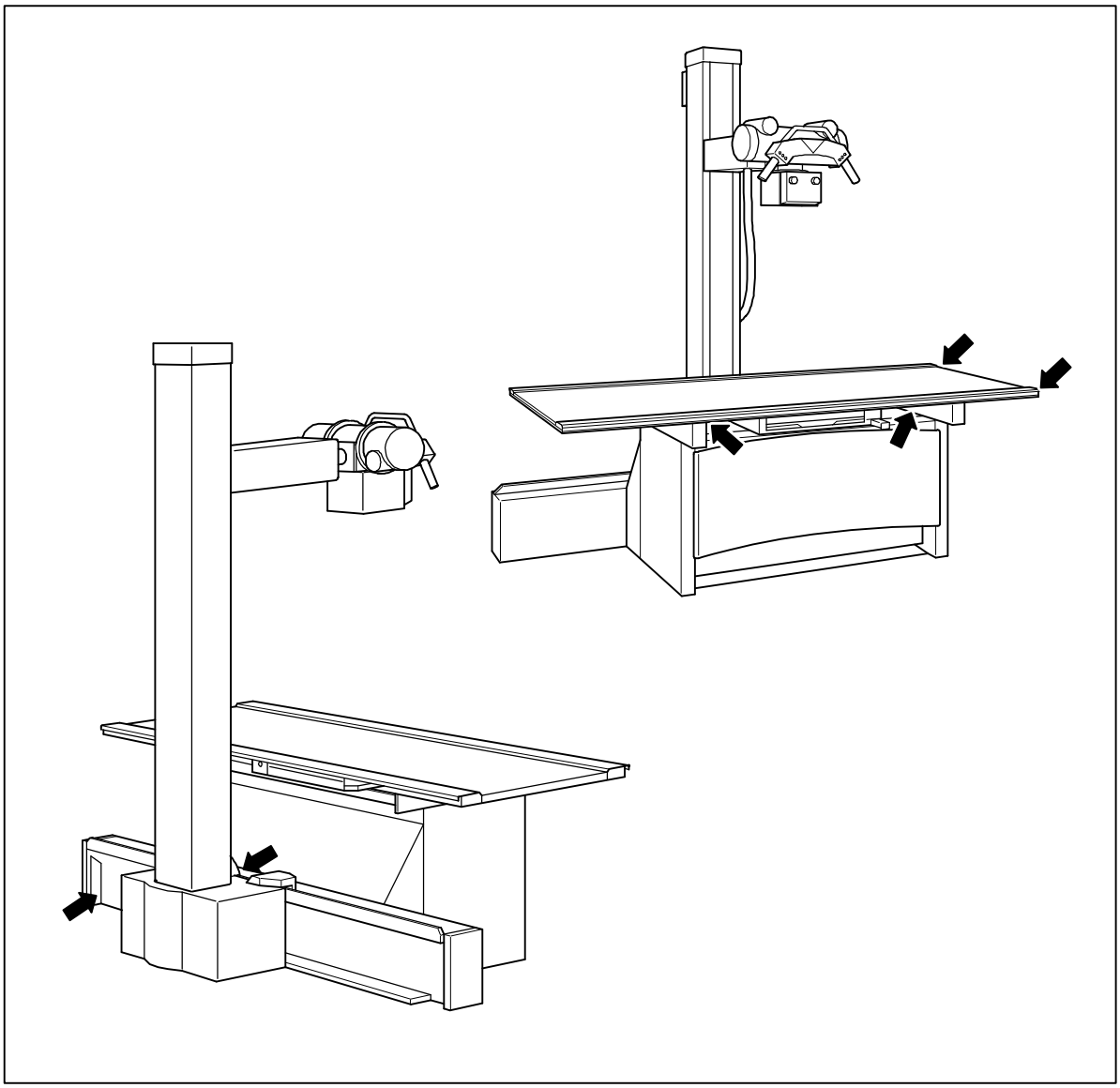
Make sure that all objects within the movement range of the radiographic equipment have been removed.

Crush Zones

The highlighted locations in the following sketch represent the danger zones in which the patient or operator can be injured by crushing or striking.

See following page

Rev. 03 © 1999 Hans Pausch Röntgengeräte Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru



Radiation Safety

The equipment does not have any control elements with which radiation can be triggered.
Triggering of exposure is made from the generator radiation-protected location.
The general regulations regarding radiation safety must be observed.

We also recommend:

1. Keep the tube current as low as possible.

2. Keep the radiation field as small as possible.

3. Maintain the max. possible distance.

4. Do not forget to provide radiation protection for the patient.

Rev. 03 © 1999 Hans Pausch Röntgengerätebau Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

Explosion Protection

This product is not intended for use in areas where there is a risk of explosion.
Only those household cleaning products whose gas-air mixture is inflammable may be used.

Electromagnetic Interference (EMI)

The product meets EMI specifications as defined in EEC Guideline 89/336.
The limit values for measurement of interference per EN 55011, Group 1, Class B and the requirements for immunity to interference per EN 50082-1, Degrees 2 and 5 are maintained.

Classification per IEC 601-1-1

Depending on the type of protection against electrical shock, the equipment corresponds to Safety Class 1 and, depending on the degree of protection, Type B.

EC Conformity

This radiographic equipment meets the basic requirements as defined by EEC Guideline 93/42 of the Committee for Medical Products, per Article 11, Paragr. 3 and the procedure listed in Appendix II.

The CE symbol is valid only for the product without the radiographic components.

Further information can be obtained upon request from:

Hans Pausch
Röntgengerätebau
Qualitätssicherung

Postfach 28 60
D-91016 Erlangen

Fax: ..49 9131 99 24 22

Environmental Conditions for Operation

Ambient temperature range	10° C to 40° C
Relative humidity in the range	20% to 80%
Ambient pressure in the range	700 hPa to 1100 hPa

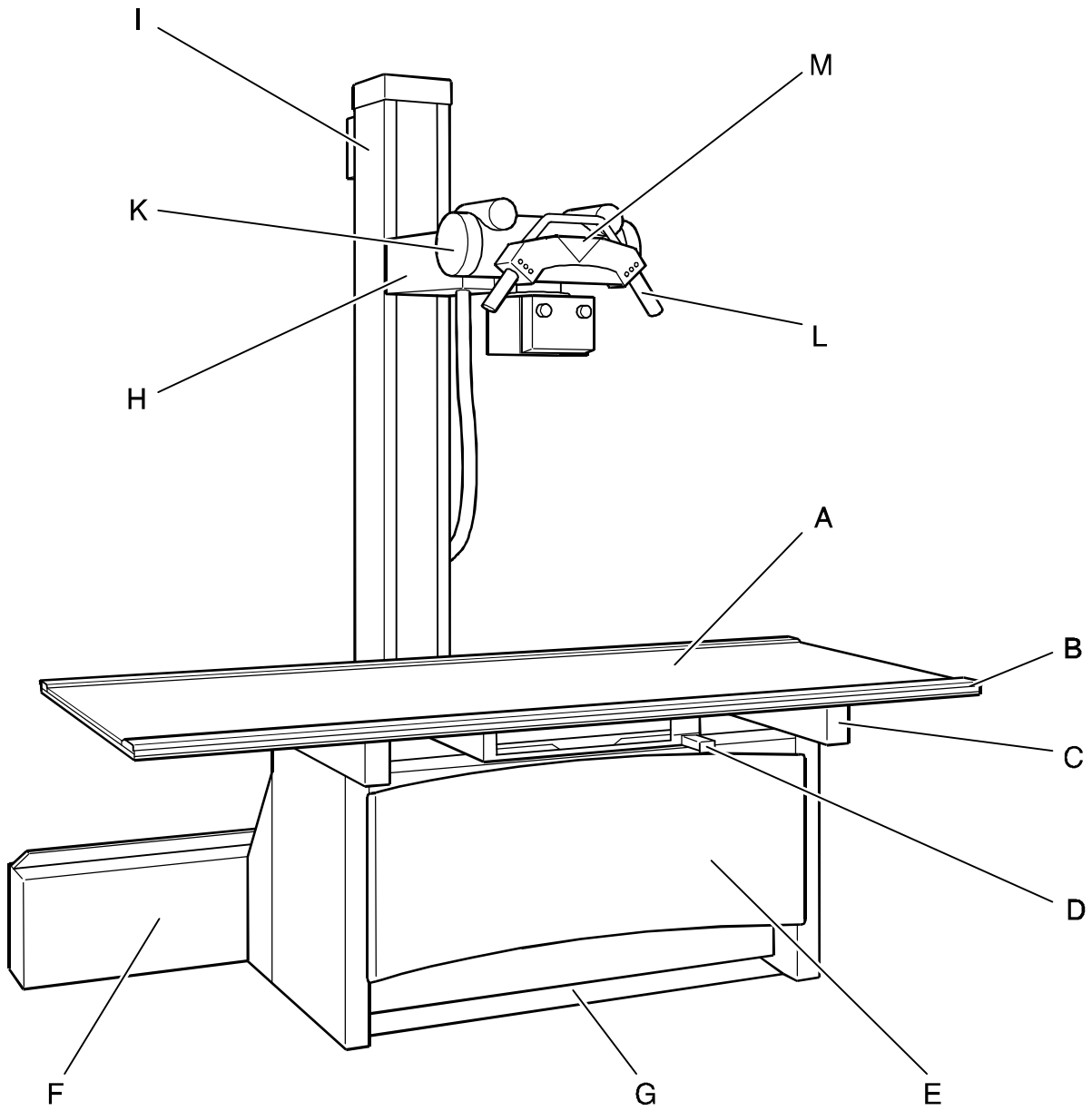
Disposal

Legal disposal regulations may exist for this product. To avoid environmental and human damage, we request that you contact your customer service department before the product is taken permanently out of operation.

Rev. 03 © 1999 Hans Pausch Röntgengeräte Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

Design Features

- Design



A Tabletop, floating, moved manually, scratch-resistant
B Profile rail, covered, smooth, for attachment of accessories
C Table upper frame
D Adjustable Bucky, moveable
E Table base, stabile, vibration-free
F Rail assembly for column stand
G Footswitch bar
H Vertical carriage with X-ray tube unit support arm
I Column stand, can be pivoted
K X-ray tube unit
L Command arm
M Angle indicator

Rev. 03 © 1999 Hans Pausch Röntgengerätebau Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

General

Brief Description

The equipment system is comprised of a patient table with the Koordinat tabletop and adjustable Bucky device, as well as a floor-mounted, guided stand column for the X-ray tube unit, collimator and command arm.

The stabile, vibration-free table base and the rail assembly for the column stand comprise a single unit.

The large-area, 220 cm-long tabletop is float-mounted, can be moved manually and is electromagnetically braked. The tabletop is designed for a maximum patient load of 136 kg. Its wide movement range (60 cm to the left, 50 cm to the right, ± 12 cm transversely) and its easy movement permit quick, effortless positioning of the patient.
The tabletop has smooth T-slot profile rails on the side which can accept accessories. The scratch-resistance surface (Resopal) and the covered, smooth rails make the tabletop especially convenient for the patient and easy to care for.

The adjustable Bucky - suitable for installation of adjustable Buckys from all well-known manufacturers - can be moved manually in the longitudinal direction under the tabletop and is braked electromagnetically. The smallest achievable film-skin distance of 70 mm assures the best geometric illustration relationships. The tabletop, which is only minimally radiation-absorbent (Al attenuation equivalency value below 0.7 mm) thus has only a minimal effect on dose. The brake for the adjustable Bucky is released by pressing a push-button on the control grip.

There is a mechanical coupling as an accessory for automatic connection of the adjustable Bucky and column stand.

The footswitch bar, close to the floor and mounting along the table base permits release of the tabletop electromagnetic brakes.

The column stand for the X-ray tube unit support arm and the X-ray tube unit is guided in the rail assembly, parallel to the table longitudinal axis.

The X-ray tube unit with collimator and command arm for the column stand is mounted on a rigid transverse arm (tube unit support arm) of the vertical carriage. It can be moved vertically and rotated around the longitudinal axis of the transverse arm. This way, the beam path can be set vertically, horizontally or obliquely. Each position is locked in place electromagnetically.

The X-ray tube unit can be pivoted around the vertical column axis with the column stand and always mechanically engages at 0° (basic position), and at ± 90° (for lateral exposures).
The standard model of the X-ray tube mount is designed for support flange mounting per DIN 6836, Form C. The max. weight of the X-ray tube unit with collimator may be 40 kg (88 lbs).

Rev. 03 © 1999 Hans Pausch Röntgengeräte Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

Area of Application

The equipment system is a universal radiographic workstation - for use in private practice, but also for use in a hospital - for Bucky exposures of excellent quality, primarily on a reclining patient. Due to the wide range of movement of the tabletop and easy operation, it is work-saving and patient-friendly. A special cassette holder is available for lateral exposures. In combination with a Bucky wall stand or with a cassette stand, exposures on a standing or sitting patient are also possible. The movement of the column stand for the X-ray tube unit for a total of ±90° also makes exposures on patient lying on a gurney or in bed possible.

Because it is not mounted either to the wall or ceiling, the location of the equipment system can be changed without problem.

Important Note

Proper use of this product requires that operating personnel be familiar with the operating instructions. They should be carefully studied prior to starting up the equipment. The section entitled, "Safety-technical Information", should be given particular attention.

Important Note for Operation

The drop brake engages immediately if movement against the end on the column stops at the top and bottom is too hard.

Rev. 03 © 1999 Hans Pausch Röntgengerätebau Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

Setup

Space Requirement

The unit is designed for stationary operation.
The space required for this is approx. 330 cm x 152 cm.
In addition, a minimum spacing of 20 cm between the column stand and the wall must be maintained.

Room Height

The height of the column stand is 234 cm. The ceiling height required for installation should be at least 245 cm. The tabletop of the equipment system has a working height of 75 cm above the floor.

Connection

The unit is designed for single phase AC current with fixed installation and, depending on the ordering information, is available in two versions.
The unit is intended only for fixed connection with universal isolation from the power net (IEC 60 l, Chap. 57.1).
It can be connected to the following nominal line voltage without a pretransformer:

Nominal voltage:	115/230 V AC
Nominal connection current:	2/1 A
Nominal frequency:	50/60 Hz
Nominal connection load:	220 VA

Line Power

Power must be led in over a 30 mA current fault interrupter installed in-house. The room installation must comply with VDE 0107.
In all countries outside the Federal Republic of Germany, the legally specified national regulations take priority and must be maintained.

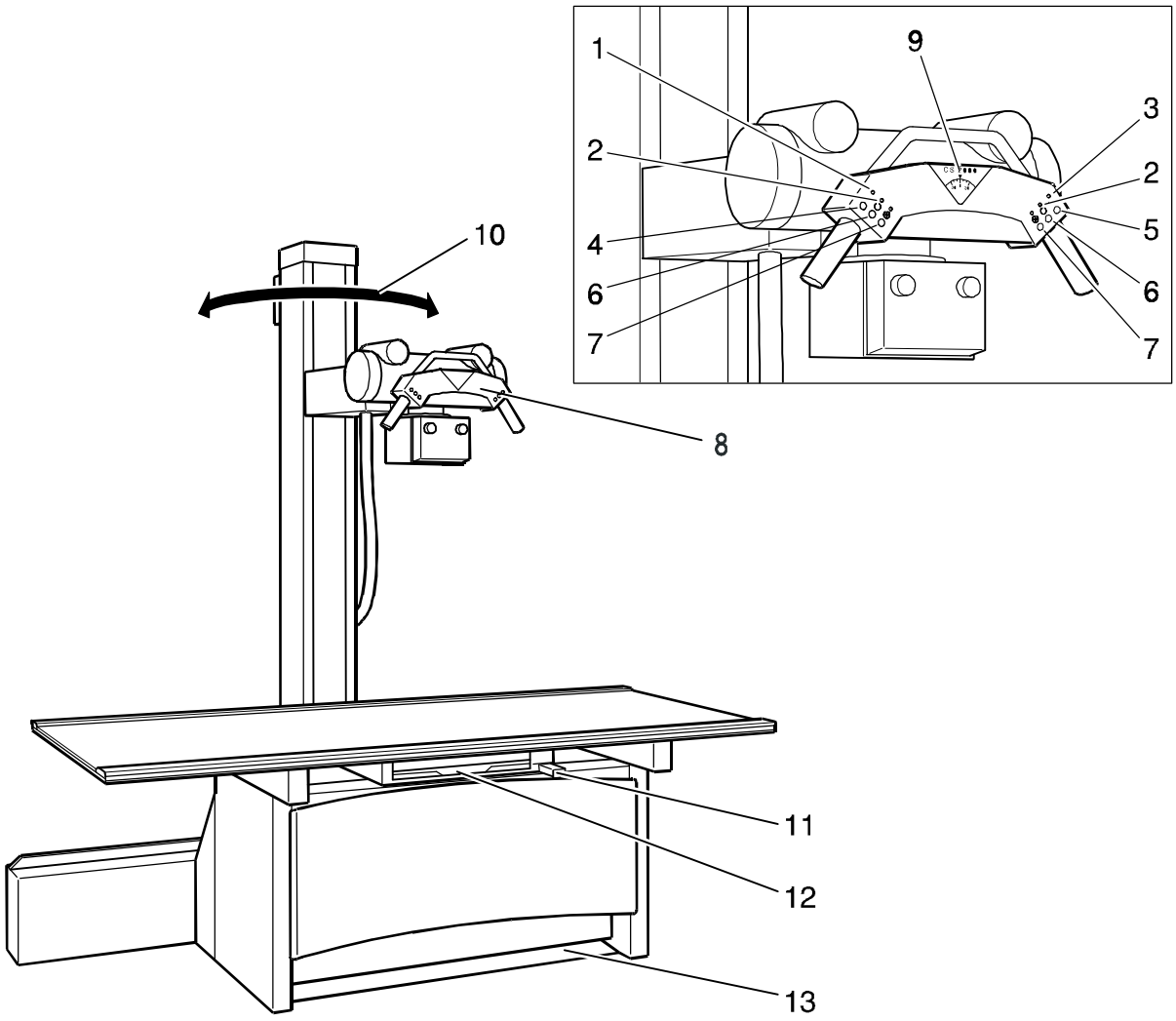
Al Equivalency Value

The attenuation equivalency value of the tabletop (patient table) is ≤ 0.7 mm.
Measured in accordance with:
DIN EN 60601-1-3 at 100 kV and a half-value layer of 3.7 mm Al
and FDA 21 CFR § 1020.30 (n) at 100 kV and a half-value layer of 2.7 mm Al.

Rev. 03 © 1999 Hans Pausch Röntgengeräte Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

Control Elements

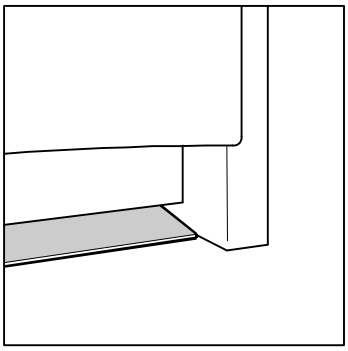
Location



1 Green LED goes on when the stand is coupled in the adjustable Bucky movement range
2 Green LED goes on when tube unit rotation is engaged
3 Green LED goes on when the default SID is reached
4 Button for longitudinal movement
5 Button for vertical movement
6 Button for turning movement
7 Button to release all stand brakes
8 Command arm with handgrips
9 Angle indicator
10 Pivot movement of the column stand by a strong motion in the direction of the pivot on the command arm
11 Pushbutton for adjustable Bucky
12 Control grip for the cassette tray
13 Footswitch strip

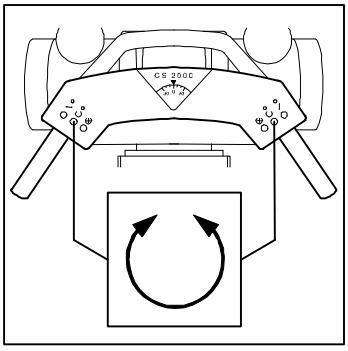
Rev. 03 © 1999 Hans Pausch Röntgengerätebau Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

Explanation of Symbols/Function



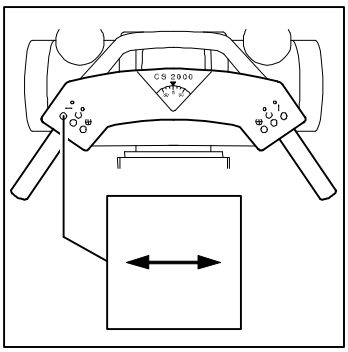
Footswitch bar 13

to release the brakes for the floating tabletop. The tabletop can be moved manually in the longitudinal and transverse directions while the footswitch bar is held down completely. The tabletop is engaged in its new working position by releasing the footswitch bar.



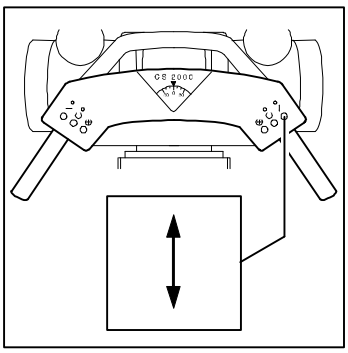
Button 6

to release the brake for rotation movement of the X-ray tube unit. The X-ray tube unit is engaged in its new working position by releasing the button.



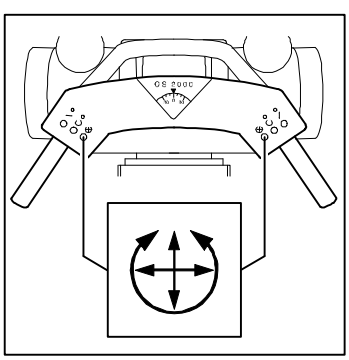
Button 4

to release the brake for longitudinal movement of the column stand with the X-ray tube unit. The X-ray tube unit is engaged in its new working position by releasing the button.



Button 5

to release the brake for vertical movement of the X-ray tube unit. The X-ray tube unit is engaged in its new working position by releasing the button.



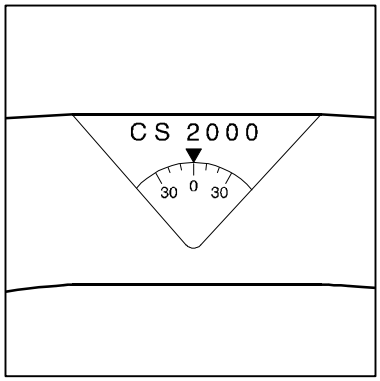
Button 7

to release all stand brakes. All movements are braked in their new working position by releasing the button.

Rev. 03 © 1999 Hans Pausch Röntgengeräte Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

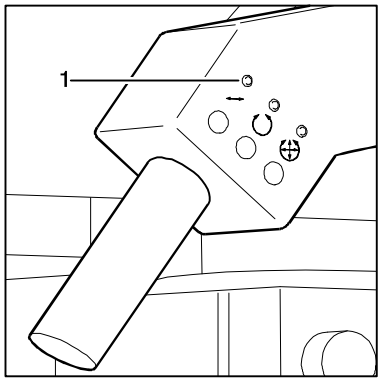
Angle indicator 9

displays the tilt angle of the X-ray tube unit to the exposure subject.



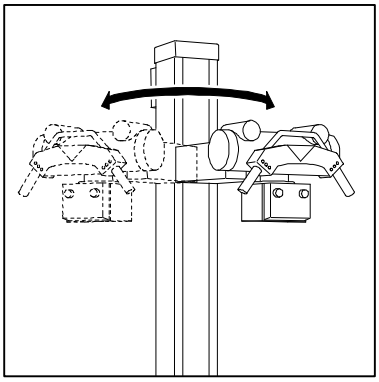
Pilot light, green 1

when lit, indicates when the column stand with X-ray tube unit is coupled with the adjustable Bucky in the movement range. When leaving the movement range, the pilot lamp goes out.



Pivoting the X-ray tube unit 10

The column stand with X-ray tube unit can be pivoted 90° to the left or right around its longitudinal axis with a strong pull on both command arm handgrips. It engages in place at both the 0° and ±90° positions.

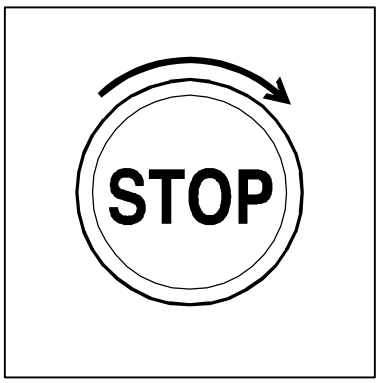


Startup

The unit system is immediately operational when it is switched on.

Emergency Off

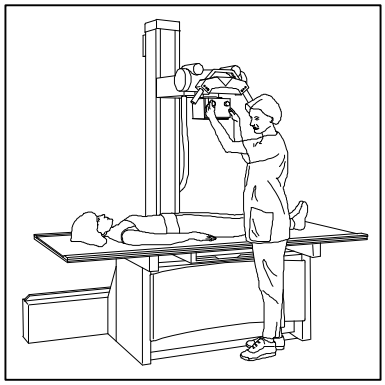
When the emergency off switch is installed in the examination room, the red button of the emergency off switch must be pressed immediately if there is any danger for the patient, operating personnel or equipment. The system may be put back into operation only when the danger has been clearly eliminated. To do this, turn the red button on the emergency off switch clockwise.



Rev. 03 © 1999 Hans Pausch Röntgengerätebau Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

Setting the Exposure Position/Exposure

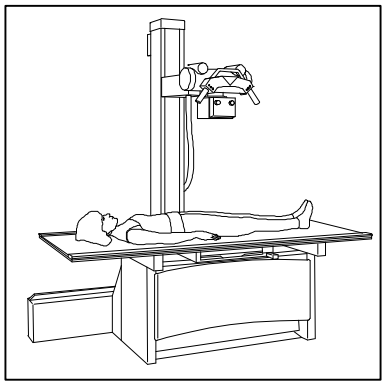
Patient positioning/centering the adjustable Bucky, object, X-ray tube unit



Positioning the patient on the tabletop.

Note

Prior to positioning the patient, move the column stand with the X-ray tube unit so that the patient cannot injure himself when he sits or lays down on the tabletop!

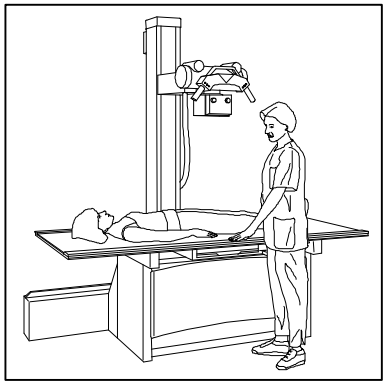


Centering the adjustable Bucky

The adjustable Bucky can also be moved to center or readjust in the exposure area.

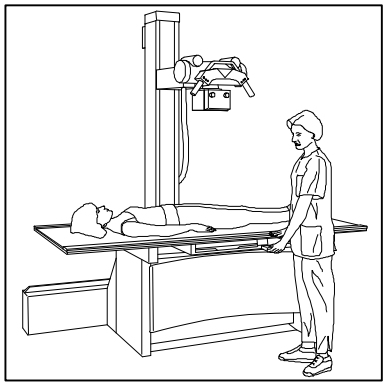
Note

This readjustment is necessary when the green lamp for the automatic stand-adjustable Bucky coupling does not go on.



Centering the exposure subject

Position the exposure subject in the central beam of the X-ray tube unit by moving the tabletop. To do this, step down completely on the footswitch bar **13**. The brakes for the floating tabletop are released. Move the tabletop, release the footswitch bar; the tabletop is locked in position.



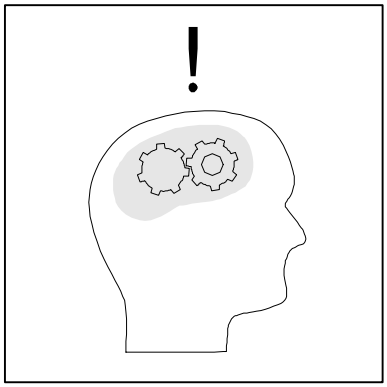
Centering the radiation field

Optimally limit the radiation field (light field!) using the radiation limiting device in the collimator (collimator operating instructions).

Rev. 03 © 1999 Hans Pausch Röntgengeräte Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

Preparing an exposure

Insert the cassette. Set the SID. Set the exposure data at the control console. Check readiness to make an exposure. Instruct the patient: Please take a breath and hold it! Trigger the exposure.

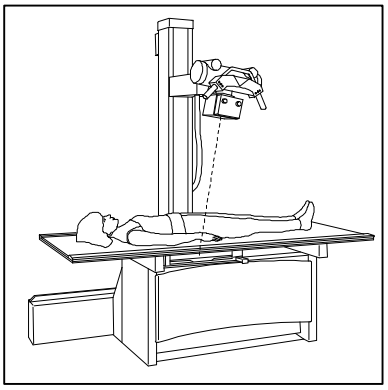


Note

Do not forget radiation protective measures for the patient, lead-rubber apron (gonad protector, etc.)!

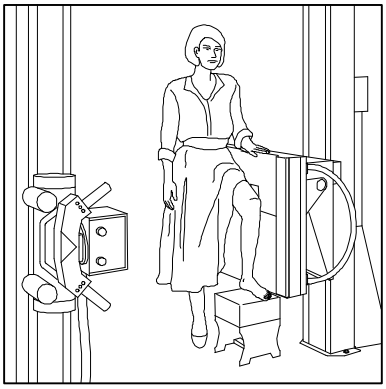
Oblique exposure

Appropriately move the column stand out over the coupling area of the automatic stand-adjustable Bucky coupling. Position the adjustable Bucky under the exposure subject. Turn the X-ray tube unit and with the light pointer in the collimator switched on, center to the middle of the adjustable Bucky.



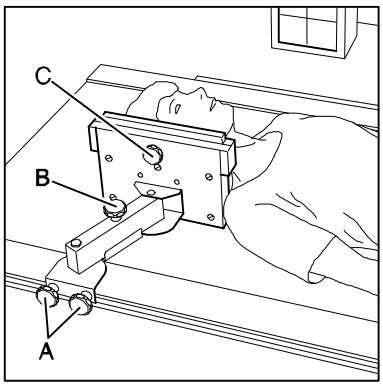
Exposure using the Bucky wall stand

Move the tabletop in opposite direction of the wall stand. Move the column stand in the longitudinal direction to the wall stand. Rotate the X-ray tube unit 90° (angle indicator!), switch on the light localizer, move the X-ray tube unit or adjustable Bucky in the wall stand appropriately in the vertical direction to center or adjust to the exposure subject.



Lateral exposure

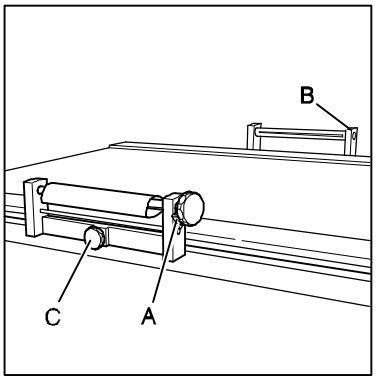
For lateral exposures using the lateral cassette holder (see also Page 16, Accessories), pivot the column stand 90°, rotate the X-ray tube unit 90° (angle indicator!). All other positioning measures have already been described.



Rev. 03 © 1999 Hans Pausch Röntgengerätebau Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

Accessories

Compression band/cassette holder/head rest/handgrips

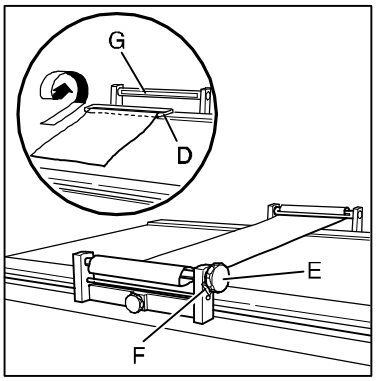


Compression band

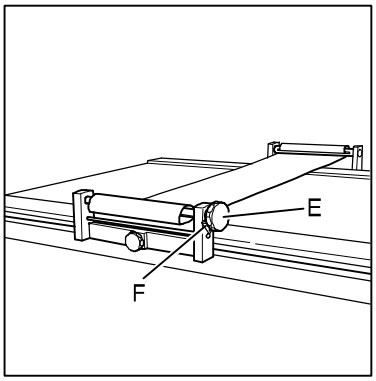
Install

Insert take-up roll **B** into the wall-side profile rail in the tabletop. Secure it in the working position using the knob on the opposite side.

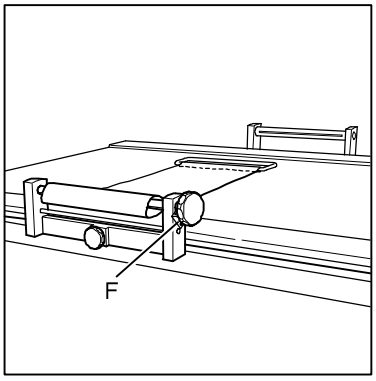
Insert tensioner **A** into the front rail. Secure the tensioner in the working position opposite the take-up **B** with knob **C**.



Press the release latch **F**. Unroll the band and stretch it across the patient.



Wrap the stretch band once around the shaft of the take-up roll. Insert bow **D** into the slot of shaft **G**. Turn knob **E** and roll up/tension the compression band.

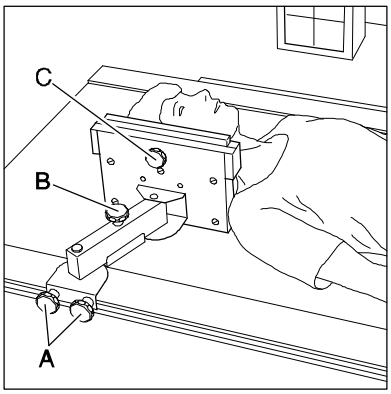


To release the band

Press release latch **F**.

Rev. 03 © 1999 Hans Pausch Röntgengeräte Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

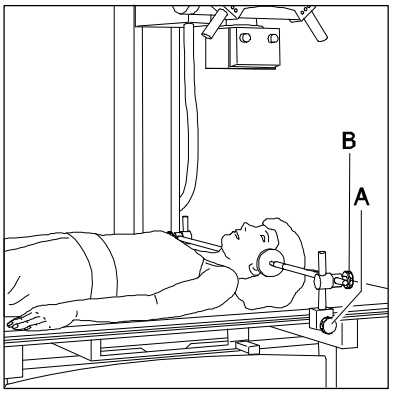
Lateral cassette holder



A lateral cassette holder permits exposures using a lateral beam path. The cassette holder is inserted into the side profile rails of the table.

Handscrew **A**: Secures the holder on the tabletop
Handscrew **B**: Holder pivoting device
Handscrew **C**: Lateral adjustment of cassette tension grip (cassette size)

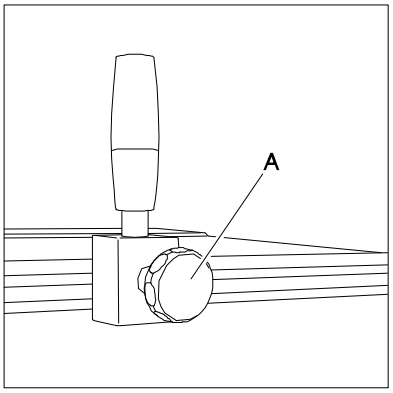
Head stabilizer



The head stabilizer is inserted into the side profile rails of the table. The stabilizer can be fixed in any desired working position. Padded supports on the adjustable arms immobilize the patient's head in the required exposure position.

Handscrew **A**: Secures the stabilizer on the tabletop
Handscrew **B**: Secures the support arm

Handgrips

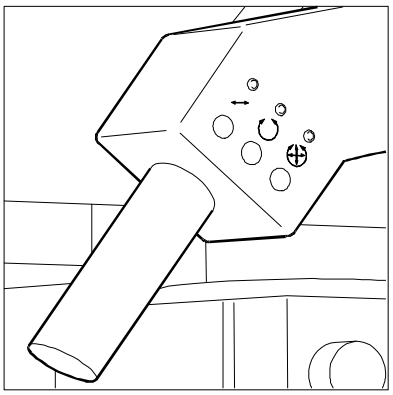


The handgrips are inserted into the side profile rails of the tabletop. They can be secured in any desired position and provide the patient with a secure hold.

Gripscrew **A**: Secures the working position

Important: The reclining patient may only use the handgrips provided as a grip. Under no circumstances may be hold on to the sides of the tabletop.

Automatic Stand-Adjustable Bucky Coupling



The automatic coupling automatically links the adjustable Bucky with the column stand in its movement range. It assures automatic centering of the X-ray tube unit to the center of the film. When this position is left, the green pilot lamp in the command arm goes off. When moving back into the movement range of the adjustable Bucky, the green pilot lamp goes on and coupling or uncoupling takes place automatically.

Rev. 03 © 1999 Hans Pausch Röntgengerätebau Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

MAINTENANCE

Important Note

As with every piece of technical equipment, this radiographic unit requires regular maintenance and upkeep to assure the operating reliability of the unit.

Operator Testing

The operator must test the radiographic unit as described below.

If there are malfunctions or other differences from normal operating behavior, switch off the unit immediately and inform customer service.
The unit may be put back into operation again only after all malfunctions have been corrected.

Daily Checks

Indicator lamps, operating elements, labels and warning labels.

Weekly Checks

All cables and their connections,

Checks by Customer Service

To achieve problem-free operation of the CS 2000, as well as to achieve safety for patients and for operating personnel, technical maintenance must be performed by customer service in intervals of 12 months.
See ”Technical Maintenance" in the installation instructions.
As part of this, it is required that the steel cable in the stand be replaced every 3 years.

Caution

If there are parts failures which affect the safety of the unit, original replacement parts must be used.

We recommend that when this work is performed, written confirmation be obtained about the type and extent of the work, and if applicable, with a statement about any changes that have been made to nominal data or about the working range, as well as with the date, name of the company performing the work and a signature.

CLEANING

Switch off the system prior to cleaning it.
Plastic surfaces may be cleaned only with a solution of soapy water because other agents (e.g. with high alcohol content) can dull or cause cracking of the surface.
No caustic, solvent or scouring cleansers or polishes may be used. Water or other liquids may not get into the unit to avoid short-circuits in the electrical installation and corrosion of parts.

Rev. 03 © 1999 Hans Pausch Röntgengeräte Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

Painted parts and aluminum surfaces may be moistened only with a damp cloth and a mild cleaning agent and wiped down with a soft cloth. Chromed parts may only be wiped down with a soft, dry cloth.

DISINFECTION

Switch off the system prior to disinfecting it. Only those disinfection methods that meet the applicable regulations and guidelines as well as explosion safety may be used. No caustic, solvent or gaseous disinfectants may be used. Spray disinfection is not recommended because if it is, disinfectants can get into the radiographic unit.

EEC Guideline 93/42 Regarding Medical Products

Article 12

Special Procedure for Systems and Treatment Equipment

Differing from Article 11, this article applies for systems and treatment equipment.
(2) Every natural or legal person who assembles products which bear the CE symbol, with the intention of putting them into use in the form of a system or as treatment equipment corresponding to their specified purpose and within their intended defined application, must provide a statement of content that

a) in mutual agreement, they have tested the products in accordance with the manufacturer's instructions and have performed the work steps in accordance with these instructions;

b) they have packaged the system or treatment equipment and have provided specific user instructions, including detailed manufacturer instructions;

c) the entire procedure was internally monitored and checked in an appropriate manner.

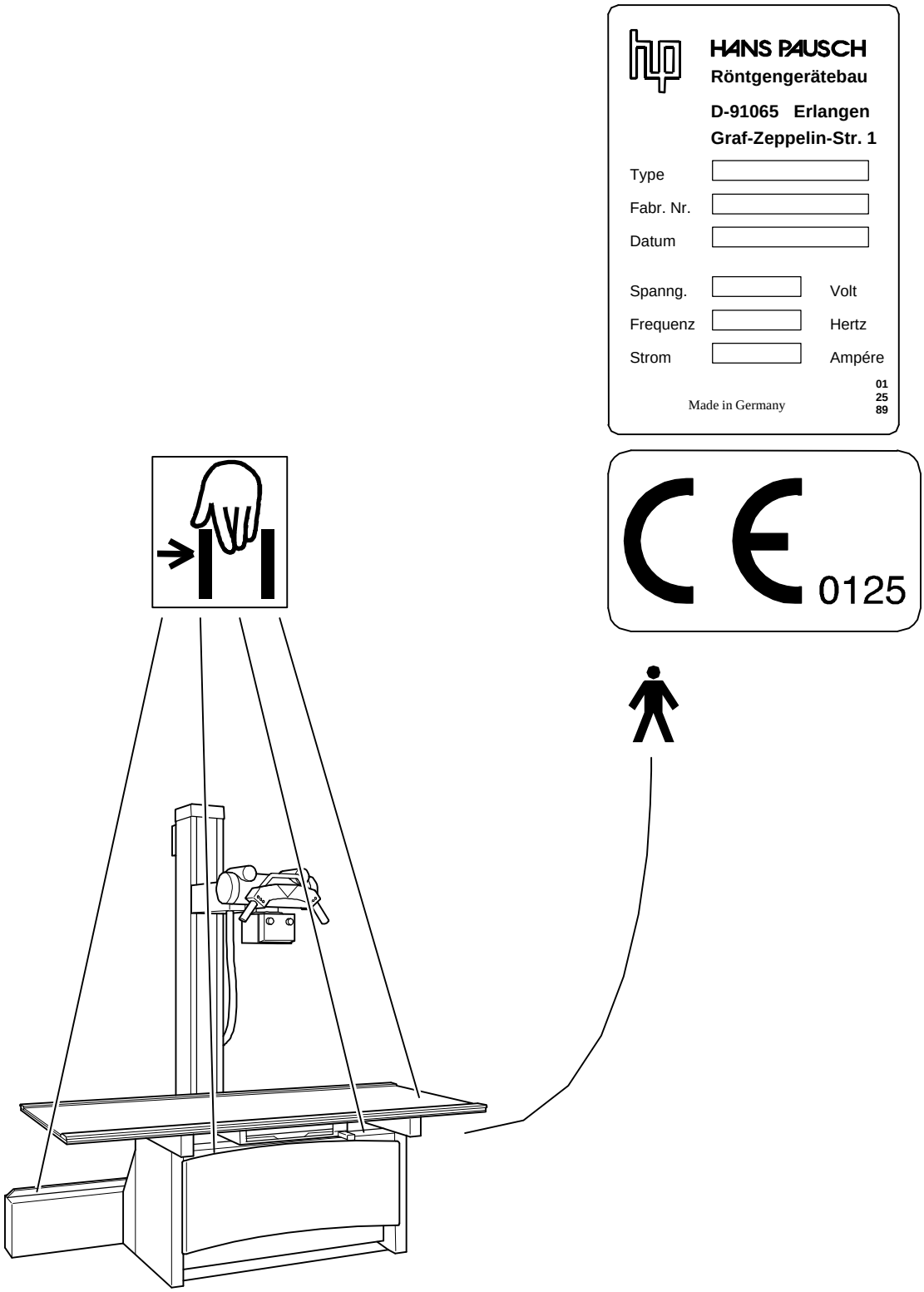
If the conditions as stated in Paragraph 2 have not been met, as would be the case when the system or the treatment equipment includes products which do not bear the CE symbol, or when the selected combination of products no longer corresponds to its original intended purpose, the system or treatment equipment shall be considered a separate product and, as such, is subject to the detailed specifications of Article 11.

The operator is responsible for maintenance of and compliance with national differences in EC countries!

Rev. 03 © 1999 Hans Pausch Röntgengerätebau Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru

Placement of Model Labels

Labeling



We reserve the right to make changes resulting from continuing technical developments.

TV/Ru

Rev. 03 © 1999 Hans Pausch Röntgengeräte Graf-Zeppelin-Str. 1 D-91056 Erlangen ALL RIGHTS RESERVED Ru